Appl. No.: 09/766,362 Patent
Art Unit: 1615 1951300-00047

Reply to Office Action of 11/30/2009

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A composition for the nasal administration of an antihistamine in a dry powder form suitable for administration of said antihistamine to the nasal region, the dry powder form made-by-a-process comprising the following steps:

providing preformed diketopiperazine microparticles between 10 and 20 microns in diameter;

suspending said diketopiperazine microparticles in an aqueous medium with an antihistamine to form a suspension; and

forming antihistamine-coated diketopiperazine microparticles by removing solvent from said suspension; microparticles comprising the antihistamine and a diketopiperazine

wherein said <u>antihistamine-coated diketopiperazine</u> microparticles are <u>sized such that the particles are preferentially retained in the nasal cavity and have a particle size of between about 10 microns and about 20 microns in diameter, and wherein more than 50% of the microparticles have a particle size greater than about 10 microns, and wherein <u>the particles are maximally retained in the nasal cavity and</u> the composition does not pass into the pulmonary system.</u>

- (Cancelled)
- 3. (Previously Presented) The composition of claim 1 wherein the antihistamine is selected from the group consisting of chlorpheniramine and azelastine.
- 4. (Previously Presented) The composition of claim 1 wherein the diketopiperazine is a substitution derivative selected from the group consisting of diketomorpholines, diketooxetanes and diketodioxanes.

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5. (Previously Presented) The composition of claim 1 wherein the diketopiperazine is formed by cyclodimerization of amino acid ester derivatives.

- 6. (Cancelled)
- 7. (Currently Amended) A drug delivery device for nasal administration comprising

an antihistamine in a dry powder form in a dosage formulation for administration to the nasal region and,

a device for delivering a measured dose of the antihistamine to the nasal mucosa,

wherein the dry powder form comprises microparticles comprising the antihistamine and a diketopiperazine coated with an antihistamine and said antihistamine-coated diketopiperazine microparticles have a particle size of between about 10 microns and about 20 microns in diameter, and wherein more than 50% of the microparticles have a particle size greater than about 10 microns, and wherein the particles are maximally retained in the nasal cavity and the composition does not pass into the pulmonary system.

- 8. (Original) The device of claim 7 wherein the device is a nasal insufflator.
- 9. (Cancelled)
- 10. (Original) The device of claim 7 wherein the antihistamine is selected from the group consisting of chlorpheniramine and azelastine.
- 11. (Previously Presented) The device of claim 7 wherein the diketopiperazine is a substitution derivative selected from the group consisting of diketomorpholines, diketooxetanes and diketodioxanes.
- 12. (Previously Presented) The device of claim 7 wherein the diketopiperazine is formed by cyclodimerization of amino acid ester derivatives.
 - 13. (Cancelled)

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14. (Currently Amended) A method of administering an antihistamine to the nasal region of a patient in need thereof, comprising:

nasally administering [[a]] the dry powder antihistamine-coated diketopiperazine microparticles of claim 1 suitable for nasal administration, wherein the dry powder form comprises microparticles comprising the antihistamine and a diketopiperazine and said microparticles have a particle size of between about 10 microns and about 20 microns in diameter and wherein more than 50% of the microparticles have a particle size greater than about 10 microns; and

wherein the composition <u>is maximally retained in the nasal cavity and does not</u> pass into the pulmonary system.

- 15. (Cancelled)
- 16. (Original) The method of claim 14 wherein the antihistamine is selected from the group consisting of chlorpheniramine and azelastine.
- 17. (Previously Presented) The method of claim 14 wherein the diketopiperazine is a substitution derivative selected from the group consisting of diketomorpholines, diketooxetanes and diketodioxanes.
- 18. (Previously Presented) The method of claim 14 wherein the diketopiperazine is formed by cyclodimerization of amino acid ester derivatives.
 - 19. (Cancelled)
- 20. (Currently Amended) The composition of claim 1 wherein said antihistamine-coated diketopiperazine microparticles are formed by spray drying.
- 21. (Currently Amended) The device of claim 7 wherein [[the]] <u>said</u> <u>antihistamine-coated diketopiperazine</u> microparticles are formed by spray drying.
- 22. (New) The composition of claim 1 wherein said antihistamine-coated diketopiperazine microparticles are formed by lyophilizing.
- 23. (New) The device of claim 7 wherein said antihistamine-coated diketopiperazine microparticles are formed by lyophilizing.